No. 12,483

IN THE

United States Court of Appeals

For the Ninth Circuit

ALBERTY FOOD PRODUCTS CO., a copartnership consisting of ADA J. ALBERTY, HARRY R. ALBERTY, HELEN M. ALBERTY HACKWORTH, KENNETH J. HACKWORTH, FLORENCE M. ALBERTY ST. CLAIR and MARGARET M. ALBERTY QUINN,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

Appeal from the United States District Court, Northern District of California, Southern Division.

APPELLANT'S REPLY BRIEF.

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PERNAU-WALSH PRINTING CO., SAN FRANCISCO

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APPELLANT'S REPLY BRIEF.

Four and one-half pages of the brief filed on behalf of the Government (page 11 to page 15, line 12, inclusive) are devoted to a discussion of unsupported charges and facts that are not part of the record on this appeal. Although the Government took the position in the District Court that the only issue in this

case was an issue of law (whether the labeling of a drug must include a statement of the conditions for which the drug is used), it now seeks to have this Court decide entirely different issues.

We do not believe, as the Government now apparently believes, that the pleadings raised the question of whether Alberty is "consistently" selling its products "on the basis of false and misleading therapeutic claims" or whether Alberty represents that it has a remedy that will prevent or cure "every affliction or aberration of mankind". If those issues are held to have been raised by the pleadings, we respectfully urge that they be first submitted to a jury, for they obviously are issues of fact. If they are held not to have been raised, the four and one-half pages of argument to which we have referred are an imposition upon this Court and should be treated as a similar imposition was treated by the District Court of Appeal of the State of California in *Cooper v. Board of Medical Examiners* (1949), 92 A.C.A. 875. The Court stated at page 877:

> "* * * Counsel for respondent is apparently not aware of some of the fundamentals governing appeals: (1) A reviewing court takes into consideration only such matters as are contained in the record on appeal; (2) unauthenticated statements in the briefs, not supported by the record, are improper and have no influence on the court; (3) Canon 22 of the Canons of Professional Ethics adopted by the American Bar Association in 1908 provides 'The conduct of the lawyer before the Court and with other lawyers should be char-

acterized by candor and fairness. It is not candid or fair for the lawyer * * * in argument to assert as a fact that which has not been proved * * * A lawyer should not * * * address to the Judge arguments upon any point not properly calling for determination by him.' * * *"

THE QUESTION OF THE JURISDICTION OF THIS COURT.

The Government first renews its motion to dismiss the appeal, presenting anew every argument which this Court rejected once before. The Government begins by assuming that the case has become moot and then proceeds to argue from that assumption. The very question at issue, however, is whether the case *has* become moot.

In *United States v. 3 Unlabeled 25-lb. Bags Dried Mushrooms* (C.C.A. 7, 1946), 157 F. (2d) 722, there was but one issue before the Court: Whether the particular shipment of mushrooms was or was not adulterated. The case was therefore truly at an end once the mushrooms were destroyed. Similarly, in *Eureka Productions v. Mulligan* (C.C.A. 2, 1940), 108 F. (2d) 760, there was but one issue before the Court: Whether the particular motion picture was or was not obscene. The case was therefore truly at an end once the motion picture was destroyed. This case, however, was not brought to an end by the destruction of the tablets, for the decision of the District Court affects not only this particular shipment, but all of

the Ri-Co Tablets which may be found throughout the United States.

Section 334 of 21 U. S. Code provides as follows:

> "* * * no libel for condemnation shall be instituted * * * for any alleged mis-branding if there is pending in any court a * * * condemnation proceeding * * * based upon the same alleged mis-branding, * * * *except that such limitations shall not apply (1) when such mis-branding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter* * * * " (Italics added.)

If the decision of the District Court is allowed to stand, the Government will thus be in a position to make multiple seizures of Ri-Co Tablets throughout the United States. The right not to be burdened with such multiple seizures is obviously a very valuable right to Alberty. This appeal was taken to protect that right and not just to save the shipment of Ri-Co Tablets involved in this case. Far from being moot, therefore, the case still presents the very live issue of whether the Government may or may not make multiple seizures of Ri-Co Tablets.

In connection with the motion to dismiss the appeal, we cited to this Court the case of *Mytinger & Casselberry v. Ewing* (U.S.D.C., D.C., 1949), 87 F. Supp. 650, in which the dangers of multiple seizures were vividly described. That case has now been reversed by the Supreme Court of the United States. (*Ewing v. Mytinger & Casselberry* (1950), 70 S. Ct.

870, 94 L. Ed. 776.) The Supreme Court upheld the multiple seizure provisions of the Act, notwithstanding the finding of the three-judge District Court that the Food and Drug Administration had acted "capriciously, arbitrarily, unreasonably, oppressively and unlawfully" (87 F. Supp. at 661) in making 11 separate seizures of the product involved in that case. Since multiple seizures are thus allowed even when they are they are capricious and oppressive, it becomes doubly important that no such seizures be made simply on the authority of an unreviewed decision of the District Court.

The Supreme Court of the United States has heretofore decided an analogous question adversely to the Government. In *Fiswick v. United States,* 329 U.S. 211, 91 L. Ed. 196, the defendant was convicted of conspiring to defraud the United States and sentenced to imprisonment for 18 months. By the time the case reached the Supreme Court, he had served his sentence, and it was accordingly contended that the case had become moot and that the appeal should be dismissed. Since the defendant was an alien and, as such, his conviction could lead to deportation and denial of naturalization, the Court held that the case had not become moot. In reversing the judgment, the Court stated:

> "Thus Fiswick has a substantial stake in the judgment of conviction which survived the satisfaction of the sentence imposed on him. In no practical sense, therefore, can Fiswick's case be said to be moot." (91 L. Ed. 203.)

In this case, Alberty has a similar stake in the decree of condemnation and that stake survived the satisfaction of the decree by the destruction of the tablets. *In no practical sense, therefore, can it be said that case has become moot.*

If this Court should feel, however, that this case has become moot, it should follow the practice adopted by the Supreme Court of the United States in such cases and, instead of dismissing the appeal, reverse the decree of condemnation and instruct the District Court to dismiss the libel. In *Brownlow v. Schwartz,* 261 U.S. 216, 67 L. Ed. 620, for example, the plaintiff sought a writ of mandate to compel the issuance of a building permit. The writ was denied by the trial Court, but the Court of Appeals reversed and ordered the permit to be issued. *The defendant failed to obtain a stay.* The permit was issued and since the building was built before the case reached the Supreme Court, that Court held that the case had become moot. It refused to allow the decision of the Court of Appeals to stand, however, even though that decision was that the permit be issued, and reversed the judgment in its entirety with instructions that the petition for the writ of mandate be dismissed.

To the same effect, see the following cases:

United States v. Hamburg-Amerikanische Co., 239 U.S. 466, 60 L. Ed. 387;

Heitmuller v. Stokes, 256 U.S. 359, 65 L. Ed. 990;

Alejandrino v. Quezon, 271 U.S. 528, 70 L. Ed. 1071;

Bracken v. Securities & Exchange Commission, 299 U.S. 504, 81 L. Ed. 374;

Leader v. Apex Hosiery Company, 302 U.S. 656, 82 L. Ed. 508.

If this appeal were now dismissed without giving Alberty an opportunity to have this Court pass upon its merits, the decision of the District Court might become *res judicata* and preclude Alberty from re-litigating, *as to any of its products,* the question of whether directions for the use of a drug are sufficient under the Act, even though the labeling does not state the conditions for which the drug is used.

On page 19 of its brief, the Government suggests that this argument (that the operation of the rules regarding *res judicata* would preclude Alberty from re-litigating the question as to any of its products) is "without substance". We perhaps do not know what "substance" means, but we nevertheless wish to point out the following: On March 5, 1950, the Solicitor General of the United States filed a petition for writs of certiorari to review the two companion cases decided by the Court of Appeals for the 8th Circuit in *United States v. Munsingwear,* 178 F. (2d) 204. The petition was granted on April 24, 1950 (94 L. Ed. 591), and the two cases are now pending in the Supreme Court of the United States where they are numbered 23 and 24. The point raised by the Solicitor General as the sole basis for his petition is the very same point, which, to the Food and Drug Administration, is without substance. On page 2 of his petition,

the Solicitor General states the "question presented" as follows:

> "Whether a judgment denying an injunction, the appeal from which has been dismissed as moot, can, despite the frustration of appellate review, stand as a bar to re-litigation of the identical issue by the same parties, but in a suit for damages."

The Solicitor General makes a very able argument in support of the proposition that the judgment should not bar re-litigation of the issue in another action between the same parties. Until he is sustained by the Supreme Court, however, it can only be said that the question is open and that a dismissal of this appeal might well later be held to bar re-litigation by Alberty of the issue litigated in the Court below.*

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*The facts in the *Munsingwear* cases were as follows: In 1944, the United States brought an action to enjoin Munsingwear from violating a price control regulation. In a separate count, the United States also asked for treble damages. By stipulation, the count for damages was held in abeyance until final adjudication of the injunction count.

In 1945 the United States brought another action for treble damages for a subsequent violation of the same price regulation and that second action was similarly continued pending the determination of the injunction count.

The question of the injunction was tried and decided in Munsingwear's favor, the Court holding that it had complied at all times with the price regulation. Pending an appeal by the United States, the commodity involved was de-controlled, so that the appeal was dismissed on the ground that the case had become moot.

Munsingwear then moved the trial Court to dismiss both the remaining count for treble damages and the separate action filed one year thereafter on the ground that the judgment on the injunction count was *res judicata*. The motion was granted, the United States appealed and the Court of Appeals affirmed the judgment of dismissal.

The Court of Appeals recognized that the cause of action passed upon by the trial Court in the injunction proceeding was not the

Under the circumstances, and in view of the uncertainty as to the applicable law, it may be that this Court will indicate in its decision, if it wishes to dismiss the appeal and does not wish to dismiss the entire case, that the judgment of the District Court shall not become *res judicata* in a subsequent proceeding based upon a different cause of action. Such a procedure was adopted by the Circuit Court of Appeals for the 1st Circuit in *Gelpi v. Tugwell,* 123 F. (2d) 377, 378, and is also suggested by the Solicitor General on page 2 of its petition for writs of certiorari in the *Munsingwear* case. Such a procedure would in no way prejudice the Food and Drug Administration, since the Ri-Co tablets involved in this case have already been destroyed, and it would give Alberty the opportunity to have the question of the sufficiency of its labels passed upon by an Appellate Court. The very same issue is admittedly involved in the *Alberty* case now pending in Washington, D. C. (See brief for appellee, page 13.) If Alberty should ultimately prevail at the trial of that case, the Food and Drug Administration will appeal. If Alberty should ultimately lose at the trial of that case, it will have to appeal or the decision of the trial court in

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same as the cause of action involved in either of the two proceedings for treble damages. Nevertheless, it held that the question of whether Munsingwear had violated the regulation had been "distinctly put in issue and directly determined" (178 F. 2d 208) in the injunction proceeding and that the question could not again be litigated between the same parties.

The only question presented in the injunction suit was the question of whether Munsingwear had violated the price regulation. Similarly, in this case, the only question is whether the Ri-Co label does or does not violate the requirements of the Act.

that case will become *res judicata*. In either event, the question of the sufficiency of the directions for use contained on Alberty's labels would then be decided on its merits.

THE MERITS OF THE APPEAL.

On the merits of the appeal, the brief for the Government is significant not so much in what it says as in what it does not say. The brief makes no mention of the regulation which the Food and Drug Administration issued before it embarked upon its present course of attempting to force the manufacturer of a drug to state the conditions for which a drug is used as part of the directions for the use of that drug.

We have demonstrated in our opening brief that the regulation itself makes a distinction between "directions for use" and "conditions" and that the former was thus clearly intended not to include the latter. The Government makes no answer to that argument. It does not even state, as it did in the District Court, that it does not wish to rely upon the regulation. Alberty does wish to rely thereon. It was promulgated by the Food and Drug Administration as *its* construction of Sec. 352(f)(1) and makes it clear that, at one time at least, the Food and Drug Administration itself recognized that, under the powers given it by the Act, it could not impose upon drug manufacturers the requirement that it now seeks to impose upon Alberty.

It has of course long been settled that the construction of a statute by the administrative agency charged with its enforcement is entitled to the highest respect and will usually not be disturbed by the Courts. *Sanford's Estate v. Commissioner of Internal Revenue,* 308 U.S. 39, 84 L. Ed. 20, and cases cited in annotation in 84 L. Ed. 28. That rule works both ways and the administrative construction of a statute binds the Government as much when it does not favor the Government's position as when it does.

Colgrove v. United States (C.A. 9, 1949), 176 F. (2d) 614, is not in point. This Court sustained a conviction of criminal contempt for violation of an injunction to which Colgrove had consented and from which no appeal had been taken. This Court accordingly did not have to decide and did not decide whether the labeling which the injunction enjoined Colgrove from using contained adequate directions for use.

The Government also relies upon *United States v. 150 Pkgs., etc.* (U.S.D.C., E.D. Mo., 1947), 83 F. Supp. 875, a case which gives no reason in support of its conclusions, and upon *United States v. Various Quantities of Article of Drug* (U.S.D.C., D.C., 1949), 83 F. Supp. 882, a case which has not yet become final. The Government also cites an article published in Vol. 5 of the Food, Drug, Cosmetic Law Journal. Since its author, Mr. Kleinfeld, is head of the General Regulations Unit, Criminal Division, Department of Justice, and is in charge of litigation under the Fed-

eral Food, Drug, and Cosmetic Act, it is hardly surprising that the views expressed in that article agree with the views expressed in the brief filed by the Government. As far as this case is concerned, however, we fail to see how the position of the Government is strengthened by the fact that the man in charge of litigation agrees with the man in charge of briefs.

The Government next contends that no information could be more essential to the consumer regarding a drug which he can purchase without prescription than a statement of the conditions for which the drug is used. We agree that no one is likely to purchase a drug without knowing the conditions for which the drug is used. That knowledge, however, must be imparted to the consumer by means other than the label. He must have it before he gets close enough to the label to be able to read its fine print. In other words, he will not buy the drug unless he learns of the conditions for which it is used from sources outside the label, as by prescription, recommendation, suggestion, or common and effective usage. By the time he sees the label, he needs only to be protected by being told *how* to use the drug for the condition for which he is purchasing it. If "4 times daily" is an adequate direction for the use of the drug in that condition, the label complies with the Act irrespective of whether it refers to that condition.

The Government's fear that, unless its new construction of the Act be adopted, the Act cannot be enforced, is groundless. We have already shown in our

opening brief that the Government is armed with all the weapons it needs for such enforcement. In any case, new weapons are manufactured by the Congress.

The Government's contention that, unless its new construction is adopted, paragraphs (a) and (j) of Section 352 are reduced to a nullity, is similarly groundless.

United States v. Dotterweich, 320 U.S. 277, and *United States v. Antikamnia Chemical Company,* 231 U.S. 654, upon which the Government relies, have nothing to do with the question now before this Court. This case is one of first impression as far as an Appellate Court is concerned and no amount of out-of-context quotations from Supreme Court decisions will make it otherwise.

To summarize: The directions printed on the label of Ri-Co Tablets are adequate for their use in all conditions for which they are prescribed, recommended, suggested, or commonly and effectively used. The Act does not require a label to include a statement of those conditions and the decree should accordingly be reversed with instructions to dismiss the libel. In the alternative, the decree should be reversed, and the question of whether the directions are adequate for the intelligent and effective use of the tablets should be left to the determination of a jury. If the case cannot be decided on its merits, the District Court should be directed to dismiss it or, in the alternative, this Court should dismiss the appeal with

an order making it clear that the decree of the District Court will not be *res judicata*.

Dated, San Francisco, California,
August 11, 1950.

Respectfully submitted,
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